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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,678	01/07/2005	Takao Fujimura	264163US0PCT	9268

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EXAMINER	
MAKAR, KIMBERLY A	
ART UNIT	PAPER NUMBER
1636	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,678	FUJIMURA ET AL.	
	Examiner	Art Unit	
	Kimberly A. Makar	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-19, drawn to methods of finding an immunosuppressive agent with a less thrombocytopenia effect, classified in class 435, subclass 7.1.

II. Claims 20-21, drawn to a kit for the identification of an immunosuppressive agent, classified in class 422, subclass 61.

III. Claims 22, 28, drawn to an HDAC inhibitor, classified in class 536, subclass 1.

IV. Claims 23-25, 29, drawn to immunosuppressive agents, classified in class 536, subclass 1.

V. Claim 27, drawn to a therapeutic method for disease, classified in class 536, subclass 1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case invention I, drawn to methods of finding an immunosuppressive agent with a less thrombocytopenia effect is

distinct from invention II, drawn to a kit for the identification of an immunosuppressive agent as the methods of invention I can be used without using the reagents of invention II. For example, the method can be done using alternate cells than the megakaryocytes provided in the kit. Additionally, invention I is a methodology and invention II is a composition. Furthermore, invention II does not require the methodology of invention I. Therefore invention I is biologically, functionally, and compositionally distinct from invention II and therefor capable of support an individual patent.

3. Inventions I and III are related as process of identifying and the product identified. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to identify another and materially different product or (2) that the product as claimed can be identified by another and materially different process (MPEP § 806.05(f)). In the instant case invention I, drawn to methods of finding an immunosuppressive agent with a less thrombocytopenia effect is distinct from invention III, drawn to HDAC inhibitors with a less thrombocytopenia effect. The methodology of invention I is distinct from the composition of invention III. Furthermore, it is possible to identify HDAC inhibitors using alternate methodologies that are unrelated to invention I. Additionally the methodology can be used to measure GATA-1 and IL-2 inhibition in a cell due to environmental factors (such as temperature or pH), and not due to the exposure of a particular inhibitor. Thus invention I is biologically, functionally, and compositionally distinct from invention III and therefor capable of support an individual patent.

4. Inventions I and IV are related as process of process of identifying and product identified. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to identify another and materially different product or (2) that the product as claimed can be identified by another and materially different process (MPEP § 806.05(f)). In the instant case invention I, drawn to methods of finding an immunosuppressive agent with a less thrombocytopenia effect is distinct from invention IV, drawn to immunosuppressive agents. The methodology of invention I is distinct from the composition of invention IV. Furthermore, it is possible to identify immunosuppressive agents using alternate methodologies that unrelated to invention I. Additionally the methodology can be used to measure GATA-1 and IL-2 inhibition in a cell due to environmental factors (such as temperature or pH), and not due to the exposure of a particular agent. Thus invention I is biologically, functionally, and compositionally distinct from invention IV and therefor capable of support an individual patent.

5. Inventions I and V are directed to related inventions. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct. Invention I, drawn to methods of finding an immunosuppressive agent with a less thrombocytopenia effect is distinct from invention V, method of treating a disease. These methods differ in scope, design, protocol,

reagents, etc. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

6. Inventions II and III are directed to related inventions. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct. Invention II, drawn to a kit for the identification of an immunosuppressive agent is compositionally distinct from invention III, HDAC inhibitors. It is possible to identify HDAC inhibitor without using the regents and protocols recited in invention II. Additionally, it is possible to use the HDAC inhibitor for alternate purposes, such as in in vitro experiments or for the treatment of diseases. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Thus invention II is biologically, functionally, and compositionally distinct from invention III and therefor capable of support an individual patent.

7. Inventions II and IV are directed to related inventions. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct. Invention II, drawn to a kit for the identification of an

immunosuppressive agent is compositionally distinct from invention IV, immunosuppressive agents. It is possible to identify HDAC inhibitor without using the regents and protocols recited in invention II. Additionally, it is possible to use the immunosuppressive for alternate purposes, such as in in vitro experiments or for the treatment of diseases. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Thus invention II is biologically, functionally, and compositionally distinct from invention IV and therefor capable of support an individual patent.

8. Inventions II and V are directed to related inventions. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct. Invention II, drawn to a kit for the identification of an immunosuppressive agent is compositionally distinct from invention V, drawn to methods for treating a disease. These inventions differ in scope and design, and have different protocols and reagents. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Thus invention II is biologically, functionally, and compositionally distinct from invention V and therefor capable of support an individual patent.

9. Inventions III and IV are directed to related inventions. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can

have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct. The HDAC inhibitors of invention III have a different composition, and have a different effect than the immunosuppressive agents in invention IV. The immunosuppressive effect of the immunosuppressive agents is not required of the HDAC inhibitors. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. Thus invention III is biologically, functionally, and compositionally distinct from invention IV and therefor capable of support an individual patent.

10. Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, invention III drawn to HDAC inhibitors can be used for other purposes that the methodology for the treatment of disease in invention V. The HDAC inhibitors can be used in in virtro experiments for the further study of GATA-1 or IL-1 pathway determination. Thus invention III is biologically, functionally, and compositionally distinct from invention V and therefor capable of support an individual patent.

11. Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, invention IV drawn to immunosuppressive agents can be used for other purposes than the methodology for the treatment of disease in invention V. The immunosuppressive agents can be used in in vitro experiments for the further study of GATA-1 or IL-1 pathway determination. Thus invention IV is biologically, functionally, and compositionally distinct from invention V and therefor capable of support an individual patent.

12. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

13. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

15. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Makar, Ph.D. whose telephone number is 571-272-4139. The examiner can normally be reached on 8AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KAM/10/27/06

DAVID GUZO
PRIMARY EXAMINER